

REMARKS

The Office Action Summary incorrectly identifies Claims 1-42 and 45-68 as being pending. In fact, Claims 1-25, 28-42, and 45-72 are pending. This discrepancy is discussed below.

PREVIOUS AMENDMENTS UNDER 37 C.F.R. § 1.111 AND EXAMINER'S AMENDMENT

On May 15, 2003, Applicants mailed an Amendment Under 37 C.F.R. § 1.111, which was received by the Patent Office on May 19, 2003, as evidenced by a return postcard. A copy of the Amendment, transmittal documents and postcard, are attached as Exhibit A. In the Amendment, Claims 1, 4-7, 11, 15-22, 25, 28-32, 40, 42, 52 and 71 were amended, and Claims 26-27 and 43-44 were canceled. Due to the cancellation of claims, upon entry of the Amendment, Claims 1-25, 28-42 and 45-72 were pending.

On June 4, 2003, in a telephonic interview with Examiner Azpuru, the Amendment Under 37 C.F.R. § 1.111 was discussed and it was further agreed to amend line 2 of Claim 1 to delete the term "systemically" by Examiner's Amendment.

A Notice of Allowance was mailed on June 10, 2003. The Notice of Allowability indicated receipt of the Amendment Under 37 C.F.R. § 1.111, referred to therein as the "amendment filed May 19, 2003." An Examiner's Amendment accompanied the Notice of Allowance, and indicated the agreed-upon amendment to Claim 1. However, the allowed claims were incorrectly identified in the Notice of Allowability as being "Claims 1-42 and 45-72." As noted above, Claims 26-27 had also been canceled in the Amendment Under 37 C.F.R. § 1.111. Therefore, the Notice of Allowability *should have* indicated that Claims 1-25, 28-42 and 45-72 were allowed.

A Status Inquiry was faxed to the Patent Office on June 20, 2003 to correct the identification of the allowed claims. In response, the Examiner mailed a Supplemental Notice of Allowability on August 6, 2003, correctly identifying Claims 1-25, 28-42 and 45-72 as being allowed.

OFFICE ACTION MAILED JANUARY 14, 2004

In the Office Action mailed January 14, 2004, Claims 1-42 and 45-68 are incorrectly identified as being pending. As detailed above, the record should reflect that Claims 1-25, 28-42, and 45-72 are pending.

A call was place to Examiner Azpura on January 26, 2004, where he indicated that the claims available to him on-line did not reflect any of the previous claim amendments. He suggested attaching a copy of the previously filed amendment to this Response so that the correct claims could be made of record. Applicants have done so, but direct the Examiner's attention to the fact that the Amendment Under 37 C.F.R. § 1.111 *does not* reflect the subsequently made Examiner's Amendment.

Accordingly, the Listing of the Claims presented here, provides a listing of the currently pending claims, as amended by the Amendment Under 37 C.F.R. § 1.111 *and* the Examiner's Amendment.

THE INVENTION

Claim 1 recites a method for treating premature ejaculation. A rapid-release pharmaceutical formulation is administered *less than 3.5 hours prior to anticipated sexual activity*, and the formulation *releases the drug at a rate that provides a systemically effective level of the drug within 3.5 hours of administration*.

Claim 40 recites a pharmaceutical formulation for treating premature ejaculation. The formulation comprises a rapid-release formulation that *releases the drug at a rate effective to provide a systemically effective level of the drug within 3.5 hours of administration*.

Claim 71 recites a packaged kit for the treatment of premature ejaculation. The kit comprises a rapid-release pharmaceutical formulation that *releases the drug at a rate effective to provide a systemically effective level of the drug within 3.5 hours of administration to a patient*.

REJECTION UNDER 35 U.S.C. §102(b) OVER DO NASCIMENTO

Claims 1-3, 8, 11, 12, 24, 35, 37-39, 67 and 68 stand rejected under 35 U.S.C. §102(b) as being anticipated by PI-9806330-8A to do Nascimento (hereinafter "do Nascimento"). However, as noted above, the identification of the pending claims is in error, and the Examiner, when

preparing this Office Action, was not reviewing the claims in their amended form. Accordingly, this response is directed to rebuttal of this rejection *as if* it had been made against Claims 1-25, 28-42, and 45-72.

do Nascimento is cited as disclosing the use of an antidepressant for the treatment of premature ejaculation. The Examiner notes that fluoxetine is specifically recited for this treatment.

Applicants' claimed method, formulation and kit relate to an as-needed basis administration, with "as-needed basis" defined in the specification to mean that the method does not involve chronic pharmacotherapy. Administration on an as-needed basis involves administration shortly before anticipated sexual activity (page 5, lines 6-8 of the specification). This typically includes administration immediately prior to sexual activity (page 9, line 21); up to about 2 or 3 hours prior to anticipated sexual activity (page 6, lines 17-19); about 0.25 to 3.5 hours, about 0.5 to 3 hours, or about 1 to 2.5 hours prior to anticipated sexual activity (page 9, lines 21-23); or within a 0.25 to 3-hour window prior to anticipated sexual activity (page 24, lines 23-24). Claim 1 was previously amended to includes these ranges in the recitation of "less than 3.5 hours." Therefore, in the method of Claim 1, the formulation is administered *less than 3.5 hours prior to anticipated sexual activity*. There is no teaching or suggestion in do Nascimento of administering an antidepressant within this time frame.

In the formulation and kit claims, the rapid-release formulation *releases the drug at a rate effective to provide a systemically effective level of the drug within 3.5 hours of administration*. There is no teaching or suggestion in do Nascimento of a formulation that provides system drug levels within this time frame.

Anticipation of a claimed invention by a prior art reference under 35 U.S.C. §102(b) requires the presence in a single prior art reference of each and every element of a claimed invention. The "rapid-release" aspect of the claimed invention is related to the recitation of administration less than 3.5 hours prior to anticipated sexual activity, as well as the formulation providing a systemically effective level of the drug within 3.5 hours of administration.

Accordingly, since do Nascimento does not teach or suggest the invention as presently claimed, Applicants assert that the invention is patentable under 35 U.S.C. §102(b).

OBJECTED TO CLAIMS

The Examiner has indicated that Claims 4-7, 9, 10, 13-23, 25-34, 36, 40-42 and 45-66 are objected to as being dependent upon a rejected claim. As further evidence that the Examiner, when preparing this Office Action, was not reviewing the claims are presently amended, Applicants note that the objected to dependent Claim 41, is in fact an independent claim.

Applicants assert that all pending claims are allowable, for reasons set forth above.

SUMMARY

The above arguments are submitted for the purpose of facilitating allowance of the Claims and a sincere effort has been made to place this application in condition for allowance. An early notice of allowance is earnestly requested.

If in the opinion of the Examiner, a telephone conference would expedite the prosecution of the subject application, the Examiner is invited to call the undersigned at (650) 330-4916.

Respectfully submitted,

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